REMARKS

Applicants wish to thank Examiner VanderVegt for conducting the telephone interview with the undersigned representative on October 20, 2003.

I. Status of the Claims

Claims 1-17 were originally filed and later canceled. New claims 18-65 were entered. Upon entering the present amendment, claims 27-65 are canceled. Claims 18-26 remain pending and are currently under examination.

II. Objections to the Specification

The Examiner objected to the specification for disclosing several amino acid sequences without using sequence identifiers, for example, on page 5, lines 1-12. Applicants respectfully note that these D-amino acid-containing sequences have not been given assigned unique identifiers (SEQ ID NOs:) under the Requirements for Patent Applications Containing Nucleotide Sequence and/or Amino Acid Sequence Disclosures, 37 C.F.R. §§ 1.821-1.825, and have not been included in the Sequence Listing previously submitted. Applicants assert that the amino acid sequences comprising D-amino acids do not conform to the definition of amino acids given in 37 C.F.R. §1.821(a)(2), where it states "[a]mino acids are those L-amino acids commonly found in naturally occurring proteins and are listed in WIPO Standard ST.25 (1998), Appendix 2, Table 3. Those amino acid sequences containing D-amino acids are not intended to be embraced by this definition."

For this reason, those amino acid sequences found on page 5, lines 1-12, do not satisfy this requirement, since on page 5, line 5, it indicates that "o is a D-amino acid", and line 10 indicates that "a is D-alanine." According to the definition that a one-letter amino acid code in lower case designates a D-amino acid, those amino acid sequences appearing in sections B, C, and D of Table II, page 36, lines 10-15 (as amended), sections B, C, and D of Table III, page 39, lines 10-15 (as amended) and TABLE IV, page 42, also need not be included in the Sequence Listing.

As such, Applicants respectfully request the withdrawal of the requirement of assigning unique sequence identifiers to the D-amino acid-containing peptide sequences (including those on page 5, lines 1-12).

III. Claim Rejections

Claims 18-26 were rejected under 35 U.S.C. §112, first paragraph, for alleged failure to comply with the written description requirement. Specifically, the Examiner asserted that the recitation of "an amino acid" for both R_1 and R_5 in claim 18 is not supported by the specification as originally filed, which contains the descriptions that "R_1 is a D-amino acid followed by alanine or lysine" and "R_5 consists of 2 or 4 amino acids followed by a D-amino acid" (page 4, lines 20-28, of the specification). Citing *Lockwood v. American Airlines Inc.* (41 USPQ2d 1961, Fed. Cir. 1997), the Examiner stated that only the subject matter expressly disclosed by a specification can serve as proper support for new claims, but what is obvious from the express disclosure cannot.

Applicants respectfully traverse this rejection. Although not disputing the Examiner's reading of *Lockwood*, Applicants note that the *Lockwood* court has further held that the specification need not disclose the claimed subject matter in "the exact terms," and that "the specification must contain an equivalent description of the claimed subject matter" if the disclosure is not in "the exact terms" (*Id*, at 1966). Applicants contend that the instant specification has provided an equivalent description of the subject matter as defined by pending claims 18-26.

The question of whether pending claim 18 and its dependent claims are properly supported by the instant specification centers around the first and last amino acids of the claimed pan DR-binding peptide, which, according to the description on page 4, lines 16-36, can be D-amino acids. The specification indicates that a pan DR-binding peptide of the present invention cannot have D-amino acids within a core binding region (page 16, lines 29-31). It is therefore clear that the first and last amino acid residues of the pan DR-binding peptides described on page 4 of the specification are not within a core binding region or at "critical contact sites." "Critical contact sites" are described on page 12, lines 10-27, of the specification as residues that "must be

present in the peptide so as to retain the ability to bind an MHC molecule and inhibit the presentation to the T cell."

The specification states that non-critical amino acids may be, among others, L- or D-amino acids:

> The non-critical amino acids need not be limited to those naturally occurring in proteins, such as L-α-amino acids, or their D-isomers, but may include non-protein amino acids as well, such as β-γ-δ-amino acids, as well as many derivatives of L-α-amino acids. As discussed, a peptide of the present invention may generally comprise either L-amino acids or D-amino acids, but not D-amino acids within a core binding region.
>
> (page 16, lines 24-31, of the specification).

The specification thus clearly provides for the interchangeability of L- and D-amino acids at non-critical sites. Since the first and last amino acids described on page 4 of the specification are not critical sites, the specification provides a pan DR-binding peptide having L-amino acids at the first and last residues, as well as one having D-amino acids at these positions.

Applicants also note that the language on page 4 merely describes R_1 and R_5 in some "preferred" "example[s]" of pan DR peptides (page 4, lines 17 and 29). This description should not be construed as the definitions of R_1 and R_5 that limit the claim scope. In fact, a "'pan DR -binding peptide' of the present invention" is defined as "a peptide capable of binding at least about 7 of the 12 most common DR alleles with high affinity" (page 7, lines 5-8). Such a peptide "may generally comprise ***either*** L-amino acids ***or*** D-amino acids" (page 16, lines 30-31, emphasis added). There is never any requirement for a pan DR-binding peptide to contain any D-amino acid.

To support this point, Applicants further point to the specification where it provides the description of how to produce a pan DR-binding peptide of the present invention. One way of producing such a peptide is via recombinant expression (*see, e.g.*, the first paragraph on page 11). Because recombinantly produced peptides will not comprise any D-amino acids, this description provides additional support for the contention that a pan DR-binding peptide of the present invention need not contain any D-amino acids.

Taken together, the instant specification clearly conveys to one of skill in the art that the present inventors had in their possession a pan DR-binding peptide as defined by the terms of claims 18-26 at the time this specification was first filed. Claims 18-26 are fully supported by the specification. Applicants therefore respectfully request the withdrawal of the written description rejection.

IV. Priority

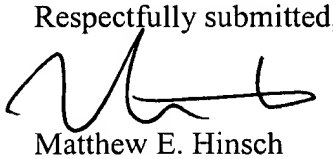
The Examiner also asserted that the present application is not entitled to priority to application 08/305,871 (the '871 application), citing the same reason based on which the pending claims 18-26 were rejected for alleged lack of the written description. As discussed in the last section, claim 18 and its dependent claims are fully supported by the '871 application. Accordingly, Applicants respectfully request that the Examiner recognize the claim of priority to the '871 application.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,



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